

### **Remarks**

The following is a response to the Office Action dated March 26, 2007.

Per the above amendment, new claims 11 and 12 have been added.

Claims 1, 5, 7<sup>1</sup> and 10 were rejected under 35 U.S.C. 102(e) as being anticipated by Ford (US 6,551,277). Claims 4 and 8 were rejected under 35 U.S.C. 103(a) as being obvious over Ford while claim 9 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Ford in view of Moberg (US 6,362,591).

The arrangement of the present invention employs a force sensor to detect pressure on the plunger of a syringe and, when this rises above a certain level indicative of an occlusion, the output of the sensor is used to trigger the motor to reverse. This continues until the force sensor detects that the pressure has reduced sufficiently.

All of the claims previously presented reflect the above arrangement. Newly added claim 11 further defines this arrangement by specifying the comparison of the force sensed by the force sensor with the contents of the memory, by the control unit, to determine whether or not the sensed force exceeds a force  $F_{\max}$ ; and if it does, signals would be sent out from the control unit to cause the drive mechanism to stop and then reverse its drive movement until the force sensed by the force sensor is reduced to a predetermined amount above  $F_{\max}$ . The support for new claim 11 is provided in the last paragraph on page 4 of the specification.

Ford (US 6551277) describes a syringe pump with a force sensor used primarily to control loading of the syringe into the pump but also to detect occlusion to flow of medication from the pump. There is no mention in this patent as to what action is taken

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<sup>1</sup> The examiner confirmed on March 29, 2007 that claim 7 indeed was rejected under this 35 U.S.C. 102(e).

when an occlusion is detected and there is certainly no mention that the pump is reversed when an occlusion is detected.

In particular, Ford teaches a plunger head retainer mechanism 10 (Fig. 2) that includes a sensor 108, in the form of a strain beam, that receives the head of the plunger at recess 105 at the front housing 100. The initialization, i.e., how the plunger head is held by arms 112 and 113 of the retainer mechanism 10, is disclosed in column 5, lines 1-45. In detail, once the head of the plunger is properly positioned relative to the pad 107 of the strain beam sensor 108 (column 5, lines 1-12), the arms 111 and 112 of the retainer mechanism would pull the plunger head 36 against the forward surface of pad 107 until a given pressure is sensed. When that happens, the motor 150 is stopped and is reversed a few steps to give a predetermined clearance between the rear surface of pad 107 and the floor of recess 105. Given the clearance between the rear surface of pad and the floor recess 105, according to Ford, the strain beam sensor then becomes responsive to pressure exerted by the retainer mechanism on the plunger 35 while the plunger is being displaced (column 5, lines 30-59). In contrast to the assertion made in the Office Action, there is no disclosure or suggestion in Ford of the pump being operable in response to a detected occlusion to reverse the drive so that the plunger may be moved along the barrel until the force detected by the force sensor falls by a predetermined amount. Thus, as noted above, Ford does not disclose, or suggest that the pump be reversed when an occlusion occurs. The only mention in Ford of any reverse pump is the positioning of the plunger relative to the strain beam and the grasping of the plunger head by the arms of the retainer mechanism when the syringe barrel is placed into the syringe pump.

Moberg (US6392591) describes a pump that monitors motor speed and, if this falls, the motor is reversed for a set distance to relieve pressure in the system. There are two essential differences between the Moberg arrangement and that of the present invention.

First, Moberg does not employ a force sensor in the manner specified by the pending claims. In fact, the whole teaching of Moberg is to avoid using pressure limit switches (col 2, lines 5 to 28).

Second, Moberg reverses the drive by a predetermined distance in contrast to the arrangement required by the claims of the present application where the drive is reversed until the sensed pressure falls by a predetermined amount.

There are two advantages achieved by the arrangement of the instant invention in which a force sensor is used rather than relying on changes in performance of the motor (as in Moberg). The first advantage is that the force sensor provides a more immediate indication of pressure rise and hence occlusion than would the motor.

The second advantage of using a force sensor is because it enables the reducing pressure to be measured during the period when a reverse drive is applied. This means that the pump can ensure that exactly the right back-off is produced. If the back-off were insufficient there might still be residual pressure in the system when the occlusion was relieved, which could cause an unwanted bolus of medication to be administered to the patient. On the other hand, if the pressure were reduced too much, it could make the occlusion more difficult to relieve or it could result in negative pressure being applied to the patient – this could result in vein collapse.

There are, therefore, real advantages to using a force sensor to control a pump that reverses when an occlusion is detected.

It is respectfully submitted that it is not appropriate to combine the teaching of Ford and Moberg because Moberg teaches specifically that pressure sensors should not be used. However, even if one were to ignore this and combine Moberg and Ford it would still not result in a pump according to the present invention because Ford only teaches that a force sensor be used to detect an occlusion. Thus, there is nothing to suggest that the

force sensor also be used to determine the extent to which a reverse drive be applied to the plunger in the manner of the present invention. The logical result of a hypothetical combination of Ford and Moberg would be that the force sensor detects the occlusion but that the motor is reversed by a predetermined increment in the manner taught by Moberg.

In light of the above, applicant respectfully submits that the instant invention, as set forth in the pending claims, is patentably distinguishable over the prior art. Accordingly, the examiner is respectfully requested to reconsider the application and pass the case to issue at an early date.

In the event the examiner has suggestions for expediting the prosecution of this case, he is respectfully requested to contact the undersigned.

Respectfully submitted,



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